

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ARROW INTERNATIONAL INVESTMENT CORPORATION

Appeal No. 99-0408
Reexamination No. 90/004,503¹

HEARD: February 10, 1999

Before McCANDLISH, *Senior Administrative Patent Judge*, ABRAMS
and McQUADE, *Administrative Patent Judges*.

ABRAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Reexamination filed December 31, 1996. This is a reexamination of Reissue Patent No. 34,993, issued July 4, 1995; which is based on Application No. 07/275,593, filed November 23, 1988, now U.S. Patent No. 4,897,077, issued January 30, 1990.

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This is an appeal from the decision of the examiner finally rejecting claims 22-41 of this reexamination application. Remaining claims 1-21 have been allowed.

The invention set forth in the claims on appeal is directed to a method of inserting an intra-aortic balloon apparatus through a patient's skin and into the femoral artery. The subject matter before us on appeal is illustrated by reference to claim 22, which has been reproduced in an appendix to the Brief.

THE REFERENCES

The references relied upon by the examiner to support the final rejection are:

Lock et al. (Lock), "Balloon dilation angioplasty of aortic coarctations in infants and children," Congenital Heart Disease, Vol. 68, No. 1 (July 1983) pp. 109-115.

Mitchell et al. (Mitchell), "Improved Balloon Catheters for Large-Vessel and Valvular Angioplasty," AJR, 142 (March 1984) pp. 571-572.

Barry et al. (Barry), "Methods and Technical Aspects of Cardiac Catheterization," Cardiac Catheterization, Vol. 1 (1980) pp. 278-307.

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The admitted prior art as set forth by the appellant in the BACKGROUND OF THE INVENTION section of the reexamination specification (admitted prior art).

THE REJECTIONS

Claim 34 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the appellant regards as the invention.

Claims 22-41 stand rejected under 35 U.S.C. § 103 as being unpatentable over the admitted prior art in view of Barry, Mitchell or Lock.

The rejections are explained in the Examiner's Answer.

The opposing viewpoints of the appellant are set forth in the Brief and the Reply Brief.

OPINION

In reaching our decision on the issues raised in this appeal, we have carefully assessed the claims, the prior art applied against the claims, and the respective views of the examiner and the appellant as set forth in the Answer and the

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Briefs. As a result of this review, we have made the following determinations.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

This claim further modifies the method steps recited in claim 34 by adding the limitation that

the dilating step (c) comprises increasing from its distal end closest to the artery to a larger outside diameter at its proximal end away from the artery.

The examiner's view is that it is unclear as to what is "increasing," and we agree. The response by the appellant in the Brief is that "[a]pplicants do not appeal the 35 U.S.C. 112 rejection of Claim 34," but will present an amendment to overcome the problem (adding --the opening-- after "increasing") if the Section 103 rejection is not sustained.

Be that as it may, appeal from the rejection was taken in Paper No. 10, and the examiner's position stands uncontroverted. The rejection therefore is sustained.

The Rejection Under 35 U.S.C. § 103

In rejections under Section 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness (see *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956

(Fed. Cir. 1993)), which is established when the teachings of the prior art itself would appear to have suggested the claimed subject matter to one of ordinary skill in the art (see *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993)). The appellant's invention relates to an improved method of inserting an intra-aortic balloon (IAB) device into the body of a patient by a sheathless insertion technique. The appellant explains in the opening paragraphs of the specification that IAB devices are introduced into the body, typically through the femoral artery, and are used to assist the pumping action of the heart, in which case "they may remain in the body for extended periods of time, such as several days or more." The appellant goes on to explain that prior art methods have placed a sheath in the artery and then inserted the balloon catheter therethrough, but that this gave rise to a number of problems that are solved by the appellant's method, in which the sheath is not utilized.

The examiner's position is that the admitted prior art teaches all of the steps recited in the appellant's claims on appeal except for inserting the IAB device without the use of a sheath, but that this is taught by all three of the

secondary references and therefore it would have been obvious to one of ordinary skill in the art to eliminate the sheath from the method of the admitted prior art. The primary argument advanced by the appellant is that the three secondary references are directed to angioplasty procedures, in which the length of time that the catheter resides in the patient is very short, whereas the final step of each of the independent claims requires "maintaining the intra-aortic balloon bladder means in place in the aorta for an extended period of time." The examiner's response to this is that the prior art technique "is not based upon long or short term procedures . . . [and] is applicable to all types of vascular procedures" (Answer, page 4).

The essence of the examiner's position is that the "time" requirement of the appellant's claims adds no patentable distinction to the method. We do not agree. The appellant's "method of inserting an intra-aortic balloon apparatus" includes as its final step "maintaining" that balloon in place for "an extended period of time."² Therefore, in order for

² We recognize that the claims are couched in terms of
(continued...)

the claims to be unpatentable, the applied prior art must establish a *prima facie* case of obviousness with regard to all of the limitations of the claim, including this one. It is our view that such is not the case.

The appellant has stated early on in the disclosure of the invention that the balloon device (IAB) that is the subject of the invention is the type used to assist the pumping action of the heart, and can be expected to remain in the patient's body for an extended period of time, such as several days or more. The prior art admitted by the appellant establishes that the method of inserting these IAB devices always included the use of a sheath. This method has been referred to during the prosecution as the "Seldinger technique," and is illustrated in Figures 1a through 1d of the appellant's application and on page 282 of the Barry reference. The admitted prior art therefore fails to disclose

²(...continued)

"[a] method of inserting an intra-aortic balloon apparatus through a patient's skin" (emphasis added). However, because the method is explained in the disclosure as being directed to balloon devices used to assist the pumping action of the heart over an extended period of time, it is our view that the claims should be interpreted broadly enough to include this as a feature of invention.

or teach the final step of the method set forth in all of the appellant's claims, that is, maintaining the IAB bladder in place for "an extended period of time," which the appellant has defined in the specification as being "several days or more."

Barry provides an overview of cardiac catheterization. It focuses on diagnostic procedures (see pages 297-298, for example), which involve maintaining the catheter in place for a short time ("following completion of hemodynamic and angiographic studies, the catheters are withdrawn" (page 280)). While the article states on page 283 that "[i]t is, of course, possible to insert an end-hole catheter . . . without the use of a sheath," it is in the context of the short-term procedures, and there is no teaching that a benefit can be gained from omitting the sheath when performing procedures in which the catheter will be in place for an extended period of time. As we view this reference, the only long-term procedure mentioned is cardiac pacing (pages 300-302), and that is in the "other procedures" discussion that appears at the end of the article, wherein the artisan is provided with no suggestion that a sheath not be utilized. In summary, it is

our view that one of ordinary skill in the art would not have found suggestion in Barry for eliminating the sheath in a situation where the catheter is to remain in place for an extended period of time, as is required by all of the claims before us.

We reach the same conclusion with regard to the other two secondary references. Mitchell teaches inserting an angioplasty balloon catheter without using a sheath (page 571, column 2). However, this reference discusses only angioplasty catheterization, and is concerned with minimizing the time the catheter is in place because blood flow then is totally occluded (page 571, column 1). There is no explicit teaching of utilizing this method in a long-term procedure, and the times for inflating and deflating the angioplasty balloon are given in seconds, from which it is apparent that the residence times of the catheters are very short. Balloon angioplasty is the subject of Lock, which also teaches inserting a balloon catheter without using a sheath. Again, there is no mention of long-term procedures, and it therefore is our view that one of ordinary skill in the art would have understood that the teaching of eliminating the sheath applies only to the

angioplasty situation, in which it would be prudent to have the catheter in place for a short a time period as possible.

The mere fact that the prior art method could be modified does not make such a modification obvious absent some suggestion for the desirability of doing so. See *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). For the reasons expressed above, it is our conclusion that one of ordinary skill in the art would not have found suggestion in any of the secondary references for eliminating the sheath when inserting an IAB device into a patient for the "extended period of time" required by the appellant's claims. This being the case, the teachings of the references fail to establish a *prima facie* case of obviousness with regard to the subject matter recited in any of the independent claims, and it follows that we will not sustain the Section 103 rejection.

SUMMARY

The rejection of claim 34 under 35 U.S.C. § 112, second paragraph, is sustained.

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The rejection of claims 22-41 under 35 U.S.C. § 103 is
not sustained.

The decision of the examiner is affirmed-in-part.

No time period for taking any subsequent action in
connection with this appeal may be extended under 37 CFR
§ 1.136(a).

AFFIRMED-IN-PART

HARRISON E. McCANDLISH)	
Senior Administrative Patent Judge)	
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)	BOARD OF PATENT
NEAL E. ABRAMS)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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JOHN P. McQUADE)	
Administrative Patent Judge)	

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Kenneth P. George
Amster, Rothstein & Ebenstein
90 Park Avenue
New York, NY 10016